EXHIBIT U

ATTACLIBATION	Α.	DICK	BAARI.	. ~ ~	* A #	E N	
ATTACHMENT	h.	RISK	MANA	∆(-F	·M	\vdash \land	11

Attached is the original Risk Analysis which was prepared in 2000	-
The Risk Analysis will be updated according to ISO 14971: 2007.	Once it is available, this
section will be updated.	

PMH-2008-08 ETHICON CONFIDENTIAL 166 of 251

ETHICO N.INC.

a Johnson Johnson company

P.O. BOX 151 SOMERVILLE, NEW JERSEY 08876-0151

November 11, 2000

Soft Prolene Mesh Device Final Design Safety Analysis (DDSA) - Summary

Overview:

The Soft PROLENE Mesh product is a single use (functioning as a bridging material) polypropylene mesh product that will be provided sterile, packaged ready for use.

An intermediate DDSA was completed and approved by the development team in March of 2000.

Intermediate DDSA Approvers:

- J. O'Malley Product Marketing
- C. Whiteman Process/Manufacturing Engineering
- M. Pamphille Corp. Quality Engineering
- K. Lessig Regulatory Affairs
- G. O'Brien Cornelia Quality Engineering
- R. Rousseau R&D

Also, a review of complaints for similar products (Mersilene and Prolene Mesh) was conducted in September of 2000 for Human Factors. (See attached report)

Conclusions:

There are 5 hazards, all at an acceptable level. No risk reduction was required.

Assumptions:

Assumptions are contained in the DDSA form (Pg. 14).

Mattmcfll Matt McGill

Quality Engineer

ETHICO N. INC.

a Johnson Johnson company

P.O. BOX 151 SOMERVILLE, NEW JERSEY 08876-0151

September 5, 2000

TO:

Matthew McGill

FROM:

R. Rousseau

CC:

Subject:

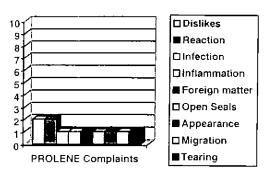
Soft PROLENE Mesh - Complaint Review of Similar Products for Human

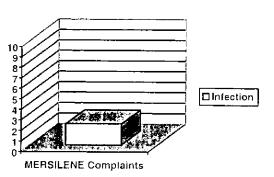
Factors

Matt,

As we had discussed during the project team meeting, held on 08/23/00, I have received an updated list of the product complaints for the standard PROLENE Mesh and for Mersilene Mesh from the World Wide Quality department(attached). The complaint listing was for the time period of May 1999 through August 2000. During this time there were a total of eleven (11) complaints for the PROLENE Mesh and two (2) complaints for the Mersilene Mesh product.

The type of complaints that were received are plotted in the following histograms:





The sales for this time period were also provided by Kiko Morillo (attached). During this time frame, $179,\!126$ sheets of PROLENE mesh and 7940 sheets of Mersilene mesh were sold. Based upon these sales results, the complaint rate for PROLENE mesh was 0.006% and for Mersilene mesh was 0.025%

The lack of a single complaint type / trend indicates that Human factors induced failure modes are not typical in either the heavy weight(PROLENE) or light weight(Mersilene) meshes. If you have any questions, please contact me at 3215.

RobertRausseau

Staff Engineer, Suture Technologies

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		TOT IMESTI	PIMI (3 X 3 PHOL)		PML (12 X 12 PROL MESH)	PMLK (2.4 X 5.4 PROL)	PMM (6 X 6 PROL MESH)	DMO / 2 / 2 / 2 / 2 / 2 / 2 / 2 / 2 / 2 /	THIS (2.3 A 4.3 PHOL MESH)	PMSK (4 X 1.8 PROL)	PMXL ()		_1	RML (12 X 12 MERS MESH)	BMS (2.5 X 4.5 MERS MECH)	┙	

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OP650-070 CP1998SEF001 Appendix I

PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	REVISION: 2
	REVISION DATE: 11/8/00
Product Name:	Soft PROLENE Mesh
Product Code:	SPMXS (1x4), SPMS (2.5x4.5),
	SPMII (3x6), SPMH (6x6),
	SPMLI (10x10), SPMXXL (12x14)
RMC:	N/A
Project Leader;	Robert A. Rousseau
ANALYSIS TEAM	ASSOCIATE NAME
Development Engineer/Scientist:	Robert A. Rousseau
Process Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Matt McGill
Regulatory Affairs:	Karen Lessig
Product Marketing:	Kiko Morillo
DISPOSITION/APPROVAL:	
And Da Ala	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Payalanment Engineer/Scientist	design to be safe for use: (Check one:) Yes;: No.
Development Engineer/Scientist	I deem this analysis to be true and a complete reflection of
	facts as known at the time of this analysis. I find this device
3.4	design to be safe for use: (Check one:): Yes;: No
Manufacturing Engineer	I doors this applicate to be seen and a section of the section of
M HMOMENT	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
r jact reflet	design to be safe for use; (Check one:) \checkmark : Yes;: No.
Quality Assurance Engineer	
Lane E Line	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
1 - wary C. Mesary	design to be safe for use: (Check one:): Yes;: No.
Regulatory Affairs 🤝 🤝 🥏	

Soft Prolene Mesh DDSA, Rev. 2

Page 1

OP650-010 CP1998SEF001 Appendix 1

PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

DESIGN SAFETY ASSESSMENT	REVISION: 2
	REVISION DATE: 11/8/00
Product Name:	Soft PROLENE Mesh
Product Code:	SPMXS (1x4), SPMS (2.5x4.5),
	SPMII (3x6), SPMH (6x6),
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RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	ASSOCIATE NAME
Development Engineer/Scientist:	Robert A. Rousseau
Process Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Matt McGill
Regulatory Affairs:	Karen Lessig
Product Marketing:	Kiko Morillo
DISPOSITION/APPROVAL:	
Development Engineer/Scientist	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:): Yes;: No.
Charlatte Whilman Manufacturing Engineer	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:): Yes;: No.
Quality Assurance Engineer	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:): Yes;: No.
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use! (Check one:): Yes;: No.
Regulatory Affairs	

Ot. J-010 CP1998SEF001 Appendix II

DEVICE DESIGN SAFETY ASSESSMENT (DDSA) SUMMARY REPORT

(Revision 2)

DEVICE: (Provide a description of the overall device system) A non-absorbable polypropylene mesh, manufactured out of 3.5-mil diameter PROLENE* monofilament fiber. The product is used to span and reinforce traumatic or surgical

wounds to provide extended support during and following wound healing (see attached Product Insert)

SCOPE of the DESIGN SAFETY ASSESSMENT: (Define the scope of this risk assessment)

Subsystem This risk assessment was completed on (check one): X Device

Component

This DDSA is applicable to the Soft PROLENE mesh product and will identify any hazards associated with this new

product offering.

Define the intended use of the reviewed item:

This mesh may be used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result (see attached Product Insert)

Briefly describe the revision to the device or sub-system which preceded a revision to the DDSA:

monofilament fiber with a new knit pattern. This new pattern, coupled with the finer diameter fiber, yields a mesh The standard non-absorbable polypropylene mesh currently marketed is manufactured out of 5-mil PROLENE monofilament fiber. The construction utilized for the Soft PROLENE mesh is manufactured out of 3.5-mil product with larger porosity, lower fabric density and improved flexibility. Revision 2 is the final DDSA.

Soft Prolene Mesh DDSA, Rev. 2

Page 2

ACTIVITY	YES/NO	FILE	COMMENT
	N.	REFERENCE	
All qualitative and quantitative characteristics that could affect safety have	YES	D&D Plan &	Statement of Requirements
even networking their defined milits.		Material	& Product Characteristics
		Specification #729-007	
The intended use of the device is clearly defined, including:	YES	Product Insert	Indivotions Comment for Co. 1
Indications/Contraindications and intended use	1		DDOLTENIE MELL
The intended user, his required skill and training			CAOLEINE IMESA AND MICESHICHE
Interaction of device with the patient as user:	_		iviesn
The operational, transport, cleaning and storage			
environments have been considered;			
Long term use of equivalent product has been considered from both the	YES	Sec Performance	Raw Materials and Indications
		Requirements/Clin	for device are the same as
Chilical/Scientific reports, both internal and published:		ical applications	Standard PROLENE mesh.
		of D&D	
The contact conditions and timing with the patient have been considered.	YES	See Performance	Raw Materials and Indications
		Requirements/Clin	for device are the same as
		ical applications	Standard PROLENE mesh.
Motoriale and assured to the		of D&D	
Practicals and components used for fabrication and manufacture have been considered.	YES	Soft PROLENE	Raw materials are chemically
(hemical noting anadiation committee of the		Mesh	unchanged – The Standard
Chemical nature, qualificative forfillulation, additives, processing aids,		Biocompatibility	PROLENE Resins utilized in
monomers, catalysts, residues:	•	Strategy	clear and blue pigmented sutures
Concentration, availability, toxicity:			have been utilized in the
Biodegradation aging and corrosion:			fabrication of this mesh.
Trevious use of this material, and long term effectiveness in equivalent			
application can be demonstrated:			
Appropriate Biocompatibility testing to EN 30993:			
The sterility of the device and its potential reuse, number of	YES	Product Insert	Raw materials are unchanged -
resterilizations possible and sterilization method, device storage, shelf-life,		Warnings section	Standard PROLENE Resin
and disposal have been considered.		ચ	
	_	1) Sterilization 2)	
		Storage Stability	

Soft Prolene Mesh DDSA, Rev. 2

clear and blue pigmented sutures tissue responses or new negative ong term implant effects are not Based upon the mechanical and Mersilene Mesh and exhibits a Mersilene Mesh and lower than develop this material, negative and suture pullout strengths of Raw materials are chemically construction exceeds the burst Raw materials are chemically PROLENE Resins utilized in flexibility that is greater than standard PROLENE mesh. chemical criteria utilized to unchanged - The Standard have been utilized in the unchanged. The revised fabrication of this mesh. anticipated A/NN/A Strategy N/AX/ANAN/A X/A YES YES Y.Z Delayed or long term use, ergonomic and accumulative effects have been Interactions with other devices or drugs, and any potential problems have The need for routine maintenance or calibration, and the method of The accuracy and precision of measurement parameters and their interpretation has been considered provision has been considered been considered. considered Appendix []

Soft Protenc Mesh DDSA, Rev. 2

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considered

(cleaning, sterilization, use, maintenance, and disposal) are available.

Device marketing brochures, or other sales literature, have been

Surgical technique, labels, warnings and other instructions for use

Manufacturing and Material specifications are available.

A requirement or finished goods specification is available

A PBOM has been defined.

Sales Literature to be developed

Indications&Claim

Yes

s Defined

Product Insert

YES YES

< Z

FG729-002 will be revised

D&D - Statement of Requirements

V/Z

YES YES MS 729-007 drafted See package Insert

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

Prolene - Polypropylene (blue DHF: Biocompatibility section Permanent prosthetic implant. nature of the compromise and training plan for the user manufacture of the material No change to raw materials If yes, please define the processes utilized in the If yes, please define the are unchanged relative to If yes, please define attach pigmented and clear). from standard PROLEME. standard PROLENE mesh . 12/2/99 memo from T Permanent prosthetic Permanent prosthetic please If yes, please training plan the limits. lf yes, Barbolt. limits. YES RESPONSE × × × × × N/A × × × × × ergonomic for toxicity construction of the device. Highlight those Is device safety/functionality compromised t_0 materials that will involve direct patient Are there any environmental factors that 4) Can the patient control or influence the 7) Does device use utilize invasive contact training of the intended user based upon the patient (such as elderly, contact could influence safety/function of the Does device use require implantation? Define the materials utilized in the Does use of the device impose any 11)Have the materials been tested for or other)? teratology, and surface tested appropriate)? .0) Have the materials been Does device use utilize diabetic, handicapped, and biocompatability? factors or effects? use of the device? with the patient? mutagenicity (as carcinogenicity, the patient? Is special device? needed? contact <u>(</u> Patient Contact 6) CHARACTERISTIC Intended Use Materials

Soft Prolene Mesh DDSA, Rev. 2

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Ot. 5-010 CP2000SEF002 Appendix III

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

RESPONSE	N/A YES COMMENT	x The Soft PROLENE Mesh is indicated for the same applications as Mersilene Mesh. The material exceeds the strength specification for Mersilene Mesh - MS726-001 and has greater suture pull-out strength than Mersilene.	<pre>X If no, proceed to the next section.</pre>		X Soft PROLENE Mesh	x If yes, please attach a listing of all by-products produced during the devices in-situ degradation	x If yes, please identify the location of appropriate reports.	X If yes, please describe how the transfer rate is controlled.	If appropriate, please attach
		12)Is the strength of load-bearing materials sufficient for the intended use?	13)Is energy delivered to and/or extracted from the patient? 14)Describe the type of energy transferred.	15)Is the energy output is controlled, in terms of quality, quantity, and time-function	ostances ed from	17)Is the device absorbable?	18)If the device is absorbable, have all of the materials identified above been tested for biocompatability at the appropriate concentrations?	<pre>19) Is the transfer rate (delivery/extraction) of substances controlled?</pre>	20)What is the maximum/minimum substance transfer rate?
	CHARACTERISTIC		4 Energy		5 Substances				

Soft Prolene Mesh DDSA, Rev. 2

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

RESPONSE	YES	If not, progetion.		If yes, please specify location of reports	If yes, please specify location of reports	X If not, please proceed to the	. 177 1	X No change to existing	polymer. Heat setting	process, utilized to stabilize the mesh is	executed at a temperature	<pre>dpp.oxlmately three times as great as the temperatures</pre>	x No change to existing materials	X No change to existing materials.	X Packaging unchanged from standard PROLENE Mesh.	X No change to existing materials - DHF: Storage Stability Committee mecting
RESP	N/A	×														
	ISSUE	21) Are biological materials processed by the device for subsequent re-use?	22) Is the device disposable?	23) Are those components contacting biological materials cleanable and sterilizable?	24) Are those components contacting biological materials compatible?	25) Is the device supplied sterile?	26) Identify the method of sterilization	27) Is the sterilization method compatible with	che materials?				28) Are the materials stable after sterilization?	29)Is the device design sterilizable?	30)Is the package designed to provide for sterilization of the device?	31) Has the shelf life of the system been determined?
	CHARACTERISTIC	6 Biological Materials				7 Sterility - Supplied Sterile										

Soft Prolene Mesh DDSA, Rev. 2

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Ot., 5-010 CP2000SEF002 Appendix III

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

	COMMENT	If not, please proceed to the next section.	If yes, please specify location of reports.	If yes, please specify location of reports.	If not, please proceed to the next section.	If yes, please specify location of reports.	If yes, please specify location of reports.	If yes, please specify location of reports.	If yes, please specify location of reports.	If yes, please specify location of reports.	If not, please proceed to the next section.	If yes, please specify location of reports.	If yes, please specify location of reports.	If yes, please specify location of reports.	If yes, please specify location of reports.
RESPONSE	N/A YES		×	u	L										
	N	×		x ces	user? x						×				
	- 1	the device re-usabl	<pre>33)Are there limitations to the number of re- use cycles?</pre>	$\sigma = 1$	the device to be sterilized by the	method of ers define	37) Is the packaging of the product during sterilization specified?	~ ບ ເ	39)Were other methods of sterilization examined?	40)Has the shelf life of the system been determined?		42)What is the effect of temperature on the system performance?	is the ef em perform	44)What is the effect of atmospheric gas concentration on system performance?	45)What is the effect of pressure on system performance?
	CHARACTERISTIC	10%			8 Sterility - Supplied Non- Sterile	7					9 Environment				

Soft Prolene Mesh DDSA, Rev. 2

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

		RESPONSE	NSE	
CHARACTERISTIC	ISSUE	N/A	YES	COMMENT
1.0 Measurements	46)Does the device make measurements?	×		If not, please proceed to the next section.
	47) Is there interference of the desired parameter with other possible measurements?			If yes, please specify location of reports.
	the accuracy o nt of use?			What is the accuracy?
	1.3	_		What is the precision?
11 interpretive	50) Are conclusions presented by the device based upon measurements, input, or acquired data?	×		
12 Interactions	51) Is the device intended to control or interact with other devices or drugs?	×		valudation reports. If not, please proceed to the next section,
P .		×		711
	53)Does the interaction render any safety or functional changes to the device?			If yes, please specify
	54)Does the interaction render any safety or functional changes to the other device?			If yes, please specify
13 Extraneous Unwanted Energy or Substances	55) Are there any unwanted outputs of energy or y substances?	×		If not, please proceed to the next section.
	56) Does noise affect the device output?			lf yes, please define the limits.
	57) Does vibration affect the device output?			If yes, please define the limits.
	58)Does heat affect the device output?			If yes, please define the limits.
81 of '	59)Does ionizing radiation affect the device output?			If yes, please define the limits.
	60)Does non-ionizing radiation affect the device output?		<u> </u>	If yes, please define the limits.

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Soft Prolene Mesh DDSA, Rev. 2

to the

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ERISTICS WORKSHEET	RESPONSE	N/A YES COMMENT	the If yes, please define the limits.		the If yes, please define the limits.	device If yes, please define the limits.	the If yes, please define the effect.	affect the If yes, please define the effect.	the	×	ice If yes, please state the limits.	If yes, please state the limits.	safety If yes, please state the limits.	the If yes, please state the limits.	If yes, please state the limits.	humidity If yes, please state the try?	ce? X If yes, please specify	
QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET 10		ISSUE	61) Does UV/visible/IR radiation affect device output?	62)Do leakage currents affect the device output?	c/magnetic fields affect	untact temperatures affect the	of chemicals affect	of waste products	67) Does discharge of body fluids affect device's output?	68) Is the device susceptible to environmental influences?	69)Do shipping temperatures affect device safety or functionality?	70)Does storage temperatures, humidity, light affect device safety or functionality?	the device affect	72)Do fluctuations in the power affect device output or safety?	73)Does variation in the operating temperature, humidity, or light affect device output or safety?	74) Does variation in the operating humi affect the device output of safety?	75)Are there essential consumables or accessories associated with the device?	Rev. 2 Page 10
III Vibradda		CHARACTERISTIC								14 Environmental Influences							1.5 Accessories	Soft Prolene Mesh DDSA Rev. 2

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

		RESI	RESPONSE	
CHARACTERISTIC	ISSUE	N/A	YES	FNEWBOO
16 Preventative Maintenance	76)Is preventative maintenance necessary?	×		If not, please proceed to the next section.
	77)Can the operator perform preventative maintenance?			
17 Calibration	79)Is calibration necessary?	×		If not, please proceed to the next section.
	80)Can the operator calibrate the device?			
	81) Is an external calibration of the device needed?			
	82) Is the calibration frequency defined?			
18 Software	83)Does the device contain software?	×		If not, please proceed to the next section.
	85)Are there means to prevent the operator from modifying the code?			
19 Shelf-life	86)Does the device have a restricted shelf life?		×	5 years - No change to existing materials - DHF: Storage Stability Committee
	87)Does the package contain an indicator for stability?		×	<u>-</u>
20 Long-term Effects	88) Are there any delayed or long-term user effects?	×		If yes, please specify.
	ADD ADDITIONAL CHARACTERISTICS, AS NEEDED			

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USE RELATED HAZARDS

Place an "X" in the box appropriate for the device being evaluated.	RESI	PONSE	ACTION
ISSUE	NO	YES	
Have safety or efficacy issues occurred in the use of predicate, or other similar, devices?	х	-	If yes, explain how this design mitigates issues.
2) Could the user incorrectly setup the device that may potentially result in a safety or efficacy event?	х		If yes, explain actions needed to address this event
3) Identify the critical steps in setting up and operating the device. Can these functions be performed adequately by all of the intended users?		х	See steps at the end of this checklist.
4) Does this device replace an existing device for the same medical procedure or indication for use?	1	x	If yes, continue to #5; if no, continue to #7
5) Does the device visually resemble the existing device?		х	If yes, continue to #6; if no, continue to #7
6) Will the device operate as intended if it is operated in the manne utilized for the existing device?	r		If yes, continue to #7; if no, explain ramifications.
7) Is the user likely to use the device in a manner other than that described in the Instructions for Use?	х		If yes, explain ramifications
8) Is special training needed for the safe and effective use of the device?	х		If yes, provide plan for accomplishing this training
9) If storage and maintenance requirements are not followed, could use of the device result in an unsafe or ineffective use?	х		If yes, provide plan to mitigate the event.
10) Is safe and effective use of the device complex? Under high stress conditions, could the user become confused such that the device results in an unsafe condition?	х		If yes, provide plan to mitigate the event
11) Are the auditory and visual alarms appropriate for all users and use environments?	Х		Device is an implant and does not have alarms.
12) If necessary device accessories are expired, damaged, missing, or different from those recommended, could use of the device result in an unsafe or ineffective treatment?	X		No accessories required for use.
13) Is safe operation of the device resistant to "typical" handling?			If no, provide plan to mitigate the event

Soft Prolene Mesh DDSA, Rev. 2

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USE RELATED HAZARDS

14.)Could device safety be affected if power is lost or disconnected (inadvertently or purposefully); if its battery is damaged, missing or dead?	х	If yes, provide plan to mitigate the event
15.)Is the status of the device's connection to the patient apparent where necessary?	Х	Device is an implant and does not connect to the patient for feedback/monitoring.

¹Critical steps in setting up and operating the device:

First the mesh is pulled for the case. The circulating nurse makes sure that the proper product was pulled for the case prior to introducing it to the sterile field. The scub nurse will either grab it out of the packet or let if fall on the mayo stand. The mesh is then given to the surgeon by the scrub nurse. If the scrub is familiar with the surgeon's needs he or she may cut or modify the mesh for the surgeon. If not, the surgeon may cut or modify to fit his needs then insert it in the patient. Then the surgeon may attach it in place using sutures, staples or a tacker.

Soft Prolene Mesh DDSA, Rev. 2

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Appendix V

DEVICE DESIGN SAFETY ASSESSMENT (DDSA) FORM Soft PROLENE Mesh Project: Intermediate - Revision 1

HAZABL	CEVEDITY	APA DIG A DOCUMENT	21010			
	of HARM	of HAZARD	LEVEL	FAULT CLASS	COMMENT	REFERENCES
Joss of Mechanical	-			CCCCC	Diel accompany Material :-	O MON LINE
Integrity	;	•	7	- ر	MISK acceptable, Material 18	DHF: D&D Statement of
۲. اعراب الا					stronger than Mersilene Mesh	Requirements, Material must
		•			with same indications. No	exceed strength criteria of
					action required.	Mersilene Mesh (MS726-001)
Jnavailable	_	2	1	Э	Risk is acceptable,	N/A
Operating					unchanged relative to	
instructions					currently marketed device.	
					No Action required.	
Frayıng		2	=	ر ر	Risk acceptable, the	Three bar knitting, by design,
					resistance to fraying is	limits the ability of the fibers to
					improved relative to currently	fray along the edges of the
					marketed Mersilene. No	mesh.
					action required.	
Learing	- 2	c.1	=	Ü	Risk acceptable, improved	DHF: D&D statement of
					relative to currently marketed	requirements and bench-top
					Mersilene mesh. No action	feasibility test reports.
=					required.	
suture Pull out	<u></u>	C-3	Ĭ	Σ	Risk acceptable, improved	DHF: Feasibility bench-rop test
					relative to currently marketed	report from Ethicon GmbH.
					Mersilene mesh. No action	
					required.	
			,			

Assumptions:

1) Only Personnel skilled in surgery have access to the device.

2) Biocompatibility and toxicology issues are proven as non-existent for PROLENE material.

3) Intended use is defined as implantation for abdominal wall repair.

4) Existing Mersilene mesh product is suitable for intended applications based upon historical results.

5) Hazards listed are new and unique to the new construction device, packaged as intended to be marketed, relative to Mersilene mesh product

Soft Prolene Mesh DDSA, Rev. 2

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ACTIONS

Polypropylene Mesh PROLENE" Soft

Nonabsorbable Synthetic Surgical Mesh



when used as a sulture, has been reported to be non-reactive and to retain its strength excellent strength, durability and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to Indefinitely in clinical use approximately 50 percent more flexible than standard PROLENE mesh. This material produce contrast striping in the mesh. The imesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). The mesh affords polypropylene identical in composition to that used in PROLENE* Polypropylene PROLENE' Soft polypropylene mesh is constructed of knitted filaments of extruded

PROLENE Soft mesh is knitted by a process which interlinks each fiber function and which provides for elasticity in both directions. This construction permits the mesh to be cut listo any desired shape or size without unraveling. The bi-directional elastic

property allows adaptation to various stresses encountered in the body.

it subject to degradation or weakening by the action of tissue enzymes. incorporating the mash into adjacent tissue. The mosh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is inflammatory reaction, which is transient and is followed by the deposition of a thin surgical wounds to provide extended support during and following wound healing Animal studies show that implantation of PROLENE mesh elicits a minimum to slight tibrous layer of tissue which can grow through the interstices of the mesh, thus PROLENE Soft mesh is a nonabsorbable mesh used to span and reinforce traumatic or

addition of a reinforcing or bridging material to obtain the desired surgical result. This mesh may be used for the repair of hernia or other fascial defects that require the

CONTRAINDICTIONS

PROLENE Soft mesh in contaminated wounds should be used with the understanding that subsequent intection may require removal of the material. should be aware that this product will not stretch significantly as the patient grows. When this mesh is used in infants or children with future growth potential, the surgeon

condition or by any other means is neither recommended nor endorsed by ETHICON, INC. PROLENE Soft mesh should $\underline{n}\underline{q}$ be flash autoclaved. autoclave conditions of 250°F (121°C) for 20 minutes. Processing under any other be adversely affected when exposed not more than one time to conventional steam PROLENE Soft mesh that has been removed from the package and reprocessed will not of the device is NOT recommended. However, testing has demonstrated that unused PROLENE Soft mesh is provided by ETHICON, INC. as a sterile product. Resterilization

If this product should become stained with blood or soiled, it should not be resterlized

sterility of the product via a validated sterilization process, as ETHICON, INC. has no control over environmental conditions the product may encounter prior to, during, or When reprocessed as outlined above, it is the responsibility of the and user to assure

A minimum of 6.5mm (1/4') of mesh should extend beyond the suture line.

ADVERSE BLACHOUS

materials, including infection potentiation, inflammation, adhesion formation, fistula Potential adverse reactions are those typically associated with surgically implantable

INSTRUCTIONS FOR USE

than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away. Some surgeons prefer to sulture an uncert section of mesh that is considerably larger (1/4° to 1/2°) apart at a distance approximately 6.5mm (1/3°) from edge of the mesh is recommended that nonabsorbable sutures be placed 6.5mm to 12.5mm

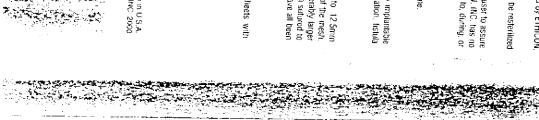
HOW SUPPLIED

PROLENE Soft mesh is available in single packets as sterile, clear sheets with

Johnnen Johnson company HICON,inc

Somerville, New Jersey 08876-0151

SETHICON, INC 2000



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PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE Appendix I

FRODUCT DEVICE DESIGN SA	PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PA
DESIGN SAFETY ASSESSMENT	REVISION: 1
	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE Mesh
Product Code:	N/A
RMC:	V/V
Project Leader:	Robert A. Rousscau
ANALYSISTEAM	ASSOCIATE NAME
Development Engineer/Scientist:	Robert A. Rousseau
Manufacturing/ Technical Services	Charlotte Whiteman
Sugineer	
Quality Assurance Engineer:	Michaelle Pamphile/G. O'Brien
Regulatory Affairs:	Karen Lessig
Product Marketing:	Jody O'Malley
DISPOSITION/APPROVAL:	
	I deem this analysis to be true and a complete reflection of
	ysis. I find this do
Development Engineer/Scientist	design to be safe for use: (Check one:); Yes;; No.
C	I deem this analysis to be true and a complete reflection of
	facts as known at the time of this analysis. I find this device
Manufacturing Engineer	design to be safe for use! (Check one:); Yes;: No
020	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Salar.	design to be safe for use! (Check one:) X _: Yes;: No
Quality Assurance Engineer	
	f deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
	design to be safe for use: (Check one.) : Yes, : No
Regulatory Affairs	

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Medical Director:

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DESIGN STREETS	DESIGN STREET ANS ESSMENT (DDSA) APPROVAT PACE
CESTON SAFE LY ASSESSMENT	REVISION: 1
	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE
Product Code:	-
RMC:	N/A
Project Leader;	Robert A. Rousseau
ANALYSIS TEAM	-
Ocvelopment Engineer/Scientist:	
Manufacturing/Technical Services	Charlotte Whiteman
Quality Assurance Engineer:	Michaella D. 1. 1. 1.
Regulatory Affairs: Karen Loccio	Karen Locaio
Product Marketing:	V 1. Aut 11
DISPOSITION/APPROVAL;	John Makey Starton
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Development Engineer/Scientist	design to be safe for use: (Check one:) : Yes: No.
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Manufacturing Engineer	design to be safe for use; (Check one.): Yes:: No.
	I deem this analysis to be mie and a complete reflection of facts as known at the time of this analysis. I find this device
Quality Assurance Engineer	design to be safe for use: (Check one:): Yes;: No.
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Regulatory Affairs	design to be safe for use; (Check one.): Yes: No.

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Medical Director;

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Appendix I

PRODUCT DEVICE DESIGN SAFETY ASSESSMENT (DDSA) APPROVAL PAGE

ANODOCI DEVICE DESIGNA	TACHOCI DEVICE DESIGN SAFETT ASSESSMENT (DDSA) APPROVAL PA
DESIGN SAFETY ASSESSMENT	REVISION: 1
	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE Mesh
Product Code:	N/A
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	ASSOCIATE NAME
Development Engineer/Scientist:	Robert A. Rousseau
Manufacturing/Technical Services	Charlotte Whiteman
Engineer	
Quality Assurance Engineer:	Michaelle Pamphile/G. O'Brien
Regulatory Affairs:	Karen Lessig
Product Marketing:	Jody O'Malley
DISPOSITION/APPROVAL:	
	I deem this analysis to be true and a complete reflection of
	facts as known at the time of this analysis. I find this device
Pevelonment Engineer/Scientist	design to be safe for use; (Check one;)
The state of the s	2
	I decid this aparitysts to be true and a complete refrection of facts as known at the time of this analysis. I find this device
May Potte Libertance	
Manufacturing Engineer	design to be sate for use. (Check one:) V. : Yes,
	I deem this analysis to be true and a complete reflection of
	facts as known at the time of this analysis. I find this device
Ouality Assurance Engineer	design to be safe for use: (Check one:); Yes;; N
	recent this analysis to be true and a complete refrection of facts as known at the time of this analysis. I find this device
	design to be safe for use; (Check one.) : Yes; : N
Regulatory Affairs	!

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Medical Director:

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DESIGN SAFETY ASSESSMENT	AFETY ASSESSMENT (DDSA) APPROVAL PAC REVISION: 1
	REVISION DATE: 3/20/00
Product Name:	Soft PROLENE Mesh
Product Code:	N/A
RMC:	N/A
Project Leader:	Robert A. Rousseau
ANALYSIS TEAM	ASSOCIATE NAME
Development Engineer/Scientist:	Robert A. Rousseau
Manufacturing/Technical Services Engineer:	Charlotte Whiteman
Quality Assurance Engineer:	Michaelle Pamphile/G. O'Brien
Regulatory Affairs:	Karen Lessig
Product Marketing:	Jody O'Malley
DISPOSITION/APPROVAL:	
Sola Ph 3/21	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:) Yes:: No.
Development Engineer/Scientist	
	I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this device
Manufacturing Engineer	design to be safe for use: (Check one:): Yes;: No.
-2 -2 -2 -2 -2 -2 -2 -2	I deem this analysis to be true and a complete reflection of
Willia VVO Con VIII V	facts as known at the time of this analysis. I find this device
Pichaell Camphile	facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:): Yes;: No.
Quality Assurance Engineer	design to be safe for use: (Check one:): Yes;: No. I deem this analysis to be true and a complete reflection of facts as known at the time of this analysis. I find this leads to the time of this analysis.
Quality Assurance Engineer	facts as known at the time of this analysis. I find this device design to be safe for use: (Check one:): Yes;: No. I deem this analysis to be true and a complete reflection of

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DEVICE DESIGN SAFETY ASSESSMENT (DDSA) SUMMARY REPORT (Revision 1 (Intermediate) = 3/20/00

DEVICE: (Provide a description of the overall device system) A non-absorbable polypropylene mesh, manufactured out of 3.5-mil diameter PROLENE* monofilament fiber. The product is used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing (see attached Product Insert)

SCOPE of the DESIGN SAFETY ASSESSMENT: (Define the scope of this risk assessment)

This risk assessment was completed on (check one): X Device

Component

Subsystem

This DDSA is applicable to the Soft PROLENE mesh product and will identify any hazards associated with this new product offering.

Define the intended use of the reviewed item.

This mesh may be used for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result (see attached Product Insert)

Briefly describe the revision to the device or sub-system which preceded a revision to the DDSA:

The standard non-absorbable polypropylene mesh currently marketed is manufactured out of 5-mil PROLENE

monofilament fiber with a new knit pattern. This new pattern, coupled with the finer diameter fiber, yields a mesh monofilament fiber. The construction utilized for the Soft PROLENE mesh is manufactured out of 3.5-mil product with larger porosity, lower fabric density and improved flexibility

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Page 2 of 2			
ACTIVITY	YES/NO /NA	FILE REFERENCE	COMMENT
All qualitative and quantitative characteristics that could affect safety have been listed including their defined limits.	YES	D&D Plan & Material Specification #729.	Statement of Requirements & Product Characteristics
The intended use of the device is clearly defined, including: Indications/Contraindications and intended use The intended user, his required skill and training Interaction of device with the patient as user: The operational, transport, cleaning and storage environments have been considered:	YES	Product Insert -	Indications Same as for Standard PROLENE Mesh and Mersilene Mesh
Long term use of equivalent product has been considered from both the positive and negative perspective. Clinical/Scientific reports, both internal and published: Device failure reports:	YES	See Performance Requirements/Clinical applications of D&D	Raw Materials and Indications for device are the same as Standard PROLENE mesh.
The contact conditions and timing with the patient have been considered.	YES	See Performance Requirements/Clinical applications of D&D	Ravy Materials and Indications for device are the same as Standard PROLENE mesh.
	YES	Soft PROLENE Mesh Biocompatibility Strategy	Raw materials are chemically unchanged – The Standard PROLENE Resins_utilized in clear and blue pigmented sutures have been utilized in the fabrication of this mesh.
The sterility of the device and its potential reuse, number of resterilizations possible and sterilization method, device storage, shelf-life, and disposal have been considered.	YES	Product Insert – Warnings section & 1) Sterilization 2) Storage Stability Strategy	Raw materials are unchanged - Standard PROLENE Resin
The accuracy and precision of measurement parameters and their	N/A	N/A	N/A

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interpretation has been considered.			
The need for routine maintenance or calibration, and the method of provision has been considered.	N/A	V/N	N/A
Interactions with other devices or drugs, and any potential problems have been considered.	YES	V /N	Raw materials are chemically unchanged – The Standard PROLENE Resins utilized in clear and blue pigmented sutures have been utilized in
Delayed or long term use, ergonomic and accumulative effects have been considered	YES	Y/Z	The raw materials utilized in the new mesh are chemically unchanged. The revised construction exceeds the burst and suture pullout strengths of Mersilene Mesh and exhibits a flexibility that is greater than Mersilene Mesh and lower than standard PROLENE mesh. Based upon the mechanical and chemical criteria utilized to develop this material, negative tissue responses or new negative long term implant effects are not
A PBOM has been defined.	No	N/A	anticipated. Will be defined during
A requirement or finished goods specification is available.	YES	D&D – Statement of Requirements	revelopment FG729-002 will be revised
Manufacturing and Material specifications are available. Surgical technique Tabels warnings and other instructions.	No	N/A	MS 729-006 will be revised
(cleaning, sterilization, use, maintenance, and disposal) are available.	YES	Product Insert	See package Insert
Device marketing prochures, or other sales literature, have been	Yes	Indications& Claims	Calor Litoroffing to be

	_		
010-6	004318866	dix V	
8	56.	vipendix	

LINE NUMBER	HAZARD	SEVERITY of HARM	PROBABILITY RISK FAULT CON	RISK	FAULT	COMMENT	REFERENCES
_	Loss of Mechanical Integrity		_	=	C	Risk acceptable, Material is stronger than Mersilene Mesh with same indications. No	DIJF: D&D Statement of Requirements, Material nust exceed strongth criteria of
C3	Unavailable Operating Instructions	_	2	_	O	action required. Risk is acceptable, unchanged relative to currently marketed device. No Action required.	Mersilene Mesh (MS726-001) N/A
2	Frayıng	_	64	=	O	Risk acceptable, the resistance to fraying is improved relative to currently marketed Mersilene. No action required.	Three bar knitting, by design, limits the ability of the fibers to fray along the edges of the mesh.
4 V	Corners Ded	62	72		O	Risk acceptable, improved relative to currently marketed Mersilene mesh. No action required.	DHF: D&D statement of requirements and bench-top feasibility test reports.
	Suture Pull out	C-1	2		Σ	Risk acceptable, improved relative to currently marketed Mersilene mesh. No action required.	DHE: Feasibility bench-top test

CONTROL PLAN

1) Only Personnel skilled in surgery have access to the device.

ppendix 1X

| 0-010 | |TSion #1 2) Biocompatibility and toxicology issues are proven as non-existent for PROLENE material.

 Existing Mersilene mesh product is suitable for intended applications based upon historical results.
 Hazards listed are new and unique to the new construction device, packaged as intended to be marketed, relative to Mersilene mesh product. 3) Intended use is defined as implantation for abdominal wall repair.

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plan.

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attach training PROLENE - Polypropylene (blue implant. DHF: Biocompatibility Section If yes, please define the nature of the compromise and implant. manufacture of the material training plan for the user. No change to raw materials pigmented and clear). The processes utilized in the are unchanged relative to The Soft PROLENE Mesh is please attach If yes, please define yes, please define indicated for the same standard PROLENE Mesh. - 12/2/99 memo from T from standard PROLENE Permanent prosthetic Permanent prosthetic Permanent prosthetic COMMENT please the limits. If yes, If yes, limits. plan +i QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET YES RESPONSE × × × × × × N/A × × × × × Soft PROLENE Mesh Project: Intermediate - Revision 1 × any ergonomic construction of the device. Highlight those Is device safety/functionality compromised materials that will involve direct patient .2) Is the strength of load-bearing materials Are there any environmental factors that 1) Is special training of the intended user 7) Does device use utilize invasive contact based upon the patient (such as elderly, diabetic, handicapped, or other)? contact could influence safety/function of the implantation? Can the patient control or influence Define the materials utilized in the 11) Have the materials been tested for carcinogenicity, teratology, and surface sufficient for the intended use? 10) Have the materials been tested mutagenicity (as appropriate)? Does use of the device impose and biocompatibility? Does device use require Does device use utilize ISSUE or effects? use of the device? with the patient? the patient? toxicity factors device? needed? contact $\hat{\sigma}$ Patient Contact CHARACTERISTIC Intended Use Materials

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Barbolt

Case 2:12-md-02327 Page 35 of 41 PageID #: 94819 Document 2775-21 Filed 09/16/16 the the Mersilene Mesh - MS726-001 and strength than Mersilene. Based the mechanical properties of the Mersilene Mesh, the material has greater suture pull-out mesh, coupled with the same Mesh. The material exceeds yes, please identify the produced during the devices If yes, please describe how strength specification for If no, proceed to the next If no, proceed to the next of all by-products applications as Mersilene upon the improvements of intended indications as If yes, please attach a location of appropriate will be sufficient for COMMENT in-situ degradation the transfer rate intended use. controlled section listing section reports. YES RESPONSE N/A ×

4) Describe the type of energy transferred

5) Is the energy output is controlled, in terms of quality, quantity, and time-

function

3) Is energy delivered to and/or extracted

from the patient?

Energy

QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET Soft PROLENE Mesh Project: Intermediate - Revision 1

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010-075

Appendix III

ISSUE

CHARACTERISTIC

×			
<pre>16)Are substances delivered to and/or extracted from the patient?</pre>	17) Is the device absorbable?	18) If the device is absorbable, have all of the materials identified above been tested for biocompatibility at the appropriate concentrations?	<pre>19) Is the transfer rate (delivery/extraction) of substances controlled?</pre>
5 Substances			

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QUALITATIVE & QUANTITATIVE CHARACTERISTICS WORKSHEET

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		COMMENT	If appropriate, please attach required information.	If not, proceed to the next section,		If yes, please specify location of reports.	If yes, please specify location of reports.	If not, please proceed to the next section.	Ethylene Oxide - Cycle "J". DHF: Sterility Section- Memo from D.Lasslett	No change to existing polymer materials and the heat setting process utilized to stabilize	the mesh is executed at a temperature approximately three times as great as the	temperatures experienced in sterilization.	No change to existing materials.	No change to existing materials.	Packaging unchanged from Standard PROLENE Mesh.	No change to existing materials - DHF: Storage
SHEET	RESPONSE	YES		_				×	<u>.</u>	×			×	×	×	×
WORK ion 1	REST	N/A		×								_				
Soft PROLENE Mesh Project: Intermediate - Revision 1		ISSUE	20)What is the maximum/minimum substance transfer rate?		22) Is the device disposable?	23) Are those components contacting biological materials cleanable and sterilizable?	24) Are those components contacting biological materials compatible?	25) Is the device supplied sterile?	26)Identify the method of sterilization	27) Is the sterilization method compatible with the materials?			28)Are the materials stable after sterilization?	29)Is the device design sterilizable?	30) Is the package designed to provide for sterilization of the device?	31)Has the shelf life of the system been determined?
		CHARACTERISTIC		6 Biological Materials				7 Sterility - Supplied Sterile	7 Sterility - Supplied Sterile							

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		COMMENT	stability Committee meeting minutes - 12/9/99	If not, please proceed to the next section.	If yes, please specify location of reports.	If yes, please specify location of reports.	If not, please proceed to the next section.	If yes, please specify location of reports.	If yes, please specify location of reports.	If yes, please specify location of reports.	If yes, please specify location of reports.	No change to existing materials DHF: Storage stability Committee meeting minutes - 12/9/99	If not, please proceed to the next section.	If yes, please specify location of reports.	If yes, please specify location of reports.
	RESPONSE	A YES										×			
	RE	N/A	1	×			× 		i				×		
4		ISSUE		the dev	33) Are there limitations to the number of reuse cycles?	34) Are there restrictions to sterilization methods utilized by the user of the device?	35) Is the device to be sterilized by the user?	36) Is the method of sterilization and cycle parameters defined?	37) Is the packaging of the product during sterilization specified?	38)Does sterilization validation data exist for the recommended sterilization cycle?	39) Were other methods of sterilization examined?	40) Has the shelf life of the system been determined?	41) Is the device intended to modify the patient environment?	42)What is the effect of temperature on the system performance?	43)What is the effect of humidity on the system performance?
		CHARACTERISTIC					8 Sterility - Supplied Non- Sterile					8 Sterility - Supplied Non- Sterile	9 Environment		

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NSE	YES COMMENT	If yes, please specify location of reports.	If yes, please specify location of reports.	If not, please proceed to the next section.	If yes, please specify location of reports.	What is the accuracy?	What is the precision?	If yes, please specify location of software validation reports	If not, please proceed to the next section.	If yes, please specify	If yes, please specify	If not, please proceed to the next section.	If yes, please define the limits.	If yes, please define the limits.	If yes, please define the limits.	If yes, please define the
RESPONSE	N/A			×				×	×			×				
	ISSUE	44)What is the effect of atmospheric gas concentration on system performance?	45)What is the effect of pressure on system performance?	es the	€.	the accuracy of t point of use?	49)1s the precision of the measurement known?	50) Are conclusions presented by the device based upon measurements, input, or acquired data?	51) Is the device intended to control or interact with other devices or drugs?	52)Does the interaction render any safety or functional changes to the device?	53)Does the interaction render any safety or functional changes to the other device?	54) Are there any unwanted outputs of energy or substances?		56)Does vibration affect the device output?	57)Does heat affect the device output?	58) Does ionizing radiation affect the device
	CHARACTERISTIC			10 Measurements					12 Interactions			13 Extraneous Unwanted Energy or Substances	•			

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38)	YES COMMENT	If yes, please state the limits.	If yes, please specify	If not, please proceed to the next section,			If not, please proceed to the next section.			If not, please proceed to the next section.			X 5 Years - No change to	existing materials - DHF; Storage stability Committee		X Expiration date labeling (5 years).	If yes, please specify.	
RESPONSE	N/A Y		×	×			×			×							×	
	ISSUE	73)Does variation in the operating humidity affect the device output of safety?	74) Are there essential consumables or accessories associated with the device?	75) Is preventative maintenance necessary?	76) Can the operator perform preventative maintenance?	17) Is a specialist needed to perform preventative maintenance?	78)Is calibration necessary?	79)Can the operator calibrate the device?	Is an e needed?	(/) <u>{</u>	83)Can the operator access the software code?	84) Are there means to prevent the operator from modifying the code?	85) Does the device have a restricted shelf			86)Does the package contain an indicator for stability?	87) Are there any delayed or long-term user effects?	ADD ADDITIONAL CHARACTERISTICS, AS NEEDED
÷	CHARACTERISTIC	1	15 Accessories	16 Preventative Maintenance			17 Calibration			16 SOLUWARE			19 Shelf-life		1		20 Long-term Effects	